

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Application No.: | 10/762,387  | Confirmation No. | 4868  |
| Applicant:       | Christopher PEARCE et al.                                 | Customer No.     | 53049 |
| Filed:           | January 21, 2004  |                  |       |
| Examiner:        | Jeffrey R. JASTRZAB                                       |                  |       |
| Group Art Unit:  | 3762  |                  |       |
| Docket No.:      | PB10056.00  |                  |       |
| Title:           | APPARATUS AND METHODS FOR DOCUMENTING MYOCARDIAL ISCHEMIA |                  |       |

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**APPEAL BRIEF**

Mail Stop Appeal Brief – Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This an appeal from the Final Rejection mailed May 1, 2006. A Notice of Appeal was filed on August 16, 2006. A Petition for a One-month Extension of Time to file this Appeal Brief is being filed simultaneously with this Appeal Brief.

Please charge the \$500.00 fee for filing the Appeal Brief to Deposit Account No. 13-2546.

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### **REAL PARTY IN INTEREST**

The real party in interest is Medtronic Physio-Control Manufacturing Corp. (now, by change of name, Medtronic Emergency Response Systems Manufacturing, Inc.) of Redmond, Washington

### **RELATED APPEALS AND INTERFERENCES**

There are no related appeals or interferences.

### **STATUS OF CLAIMS**

Claims 1-79 are pending.

Claims 1-79 are on appeal in this case.

Claims 1-79<sup>1</sup> stand rejected under 35 U.S.C. § 102(c) or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over U.S. Published Patent Application No. US2005/0004485 ("Crosby").

### **STATUS OF AMENDMENTS**

The claims have not been amended under 37 C.F.R. § 1.116. The claims stand as listed in the Amendment filed January 25, 2006.

### **SUMMARY OF CLAIMED SUBJECT MATTER**

Line numbers refer to the specification as originally filed. References to text and drawings are intended as examples and not as exhaustive lists of relevant text and drawing references.

(Claim 1) An apparatus for documenting the myocardial ischemia of a patient's heart includes an ECG monitor and data collector (Fig. 1, no. 12) configured to receive electrocardial data about the patient's heart (para. 20, lines 1-4), a cardiac marker data

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<sup>1</sup> The Final Office Action dated 05/01/2006 ("Final Action") lists claims 1-78 as pending, and lists claims 1-78 in the claims rejections. Claim 79 is not mentioned in the Action. Applicant has assumed that this is a clerical (typographical) error and references to "1-78" in the Final Action were meant to be "1-79".

collector (Fig. 1, no. 22) configured to receive cardiac marker data about the patient's heart (para. 23, lines 1-4), and a data processing and recording module (Fig. 1, nos. 14/18) in electrical communication with the ECG monitor and data collector and the cardiac marker data collector. The recording module is configured to record the ECG data and cardiac marker data (para. 24, lines 1-6), and to generate a prompt to a user to perform a cardiac marker test (para. 26, lines 1-4 and 6-8).

(Claim 22) A method for documenting the myocardial ischemia of a patient's heart includes obtaining electrocardial data about the patient's heart (Fig. 3, no. 302); providing a prompt for the performance of a cardiac marker test (Fig. 3, no. 308); receiving results of the cardiac marker test (Fig. 3, no. 314; storing the electrocardial data and cardiac marker test results in a patient report (Fig. 3, no. 316); and displaying the report (Fig. 3, no. 324).

(Claim 40) An apparatus for documenting the myocardial ischemia in a patient's heart includes means for receiving electrocardial data about the patient's heart (Fig. 1, no. 12), means for receiving cardiac marker data about the patient's heart (Fig. 1, no. 22), and means for processing the electrocardial data and cardiac marker data (Fig. 1, no. 14). The means for processing the electrocardial data and cardiac marker data includes means for generating a prompt to perform a cardiac marker test (para. 26, lines 1-4 and 6-8); means for recording the electrocardial data and cardiac marker data into a patient record (para. 25, lines 14-15); and means for displaying the patient record (para. 25, lines 14-15).

(Claim 62) A medical apparatus of the type that is configured to monitor the ECG waveform of a patient includes a cardiac marker data collector (Fig. 1, no. 22) configured to receive cardiac marker data about the patient's heart (para. 23, lines 1-4); a data processor (Fig. 1, no. 14) in electrical communication with the cardiac marker data collector; a memory module (Fig. 1, no. 18) in electrical communication with the data processor and configured to record the ECG waveform and cardiac marker data (para. 24, lines 1-6); and a display module (Fig. 1, no. 24) in electrical communication with the data processor and configured to display the ECG waveform and/or the cardiac marker data (para. 25, line 13). The data

processor is configured to generate a prompt to a user to perform a cardiac marker test (para. 26, lines 1-4 and 6-8).

### **GROUND S OF REJECTION TO BE REVIEWED ON APPEAL**

1. Whether the subject matter of claims 1-79 is anticipated by US Patent Publication No. 2005/0004485 ("Crosby") under 35 U.S.C. § 102(e).
2. Whether the subject matter of claims 1-79 is obvious in view of Crosby, under 35 U.S.C. § 103(a).

### **ARGUMENTS**

#### **1. Claims 1-79 are not anticipated by Crosby under 35 U.S.C. § 102(e).**

The Examiner has rejected claims 1-79 under 35 U.S.C. § 102(e) as being anticipated by Crosby. To be anticipated by a reference under 35 U.S.C. § 102(e), each and every limitation in the claim must be present in the cited reference.<sup>2</sup>

The independent claims on appeal all have limitations which are not found in the Crosby reference. Independent claim 1 includes the limitation that the data processing and recording module is configured "to generate a prompt to a user to perform a cardiac marker test." Independent claim 22 includes the limitation of the step of "providing a prompt for the performance of a cardiac market test." Independent claim 40 includes the limitation that the means for processing electrocardial and cardiac marker data "comprises means for generating a prompt to a user to perform a cardiac marker test". Independent claim 62 includes the limitation that the data processor is "configured to generate a prompt to a user of the apparatus to perform a cardiac marker test." Each of the remaining claims on appeal is a dependent claim depending from on of these independent claims.

An apparatus that prompts a user to perform a cardiac marker test on a patient, or a method which includes a step of prompting a user to perform a cardiac marker test is

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<sup>2</sup> Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)

nowhere disclosed in Crosby. The Examiner essentially admits this where the Final Action states:

As such, it would seem that a physical prompt would be an inherent part of the Crosby et al. system. Alternatively even if an actual prompt does not appear on a screen, or an audible or other prompt is given in this system, it would have been an obvious design choice to have altered the automatic steps of Crosby et al. to make them manual, or in a prompted order....<sup>3,4</sup>

In other words, provision of a prompt to administer a cardiac marker test is not found explicitly in Crosby's teachings.

Not only does Crosby not explicitly teach a prompt to perform a cardiac marker test, it doesn't imply or suggest a prompt either. Crosby teaches a risk stratification algorithm which assumes that a cardiac marker test will be employed. The Examiner has said that Crosby "appears to include an embodiment at parag. 62 that, after ECG analysis alone, resorts to in vitro testing if a condition exists."<sup>5</sup> But what paragraph 62 of Crosby actually says is:

The algorithm may also take into account the probability that a patient has the clinical condition as determined by the analysis of the ECG alone..., and combining this probability with probabilities determined by the results of the in vitro diagnostic tests."<sup>6</sup> [Emphasis added].

This teaches an algorithm where both an ECG and an in vitro test are done and the results of the tests are combined. Crosby teaches a method, intended for use by a physician<sup>7</sup>, for diagnosing a clinical event occurring in a patient which includes obtaining from the patient at least one sample from the blood stream and conducting an in vitro assay.<sup>8</sup> Crosby does not envision a system where in some cases, only an ECG test is done while in others, an ECG and a cardiac marker test is done. In addition, Crosby states that

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<sup>3</sup> Final Action, page 3, lines 9-13.

<sup>4</sup> The Examiner's assertion of an "obvious design choice" is discussed below in section 2 of the Arguments.

<sup>5</sup> Final Action, page 3, lines 6-7.

<sup>6</sup> Crosby, para. 62, lines 1-7.

<sup>7</sup> See, e.g., Crosby para. 3, lines 1-2 ("The chest pain patient presents a diagnostic nightmare for the emergency room physician."); and para. 31, lines 1-2.

<sup>8</sup> Crosby, para. 36, lines 1-5.

Note that the sequence of events of performing the ECG and in vitro diagnostic tests is unimportant, and they can be performed in the order given described above, or any other order, or simultaneously.<sup>9</sup>

Crosby's method always includes an in vitro assay and the in vitro diagnostic test may be done at any point in the sequence of event. Therefore, a prompt to give a cardiac marker test is not needed since a physician choosing to employ Crosby's method will, by definition, know that an in vitro diagnostic test is needed to perform it (since it is an integral part of Crosby's diagnostic method), and the point in the process in which the physician performs this test doesn't matter. The starting point of Crosby's teachings is the assumption that in vitro test data are available and Crosby's teaching go from there to describe an algorithm using such data. For at least these reasons, it cannot be said that the giving of a prompt to perform a cardiac marker test is an inherent part of the Crosby system.

For at least these reasons, independent claim 1 and claims 2-8 and 11-20 which depend therefrom, independent claim 22 and claims 23, 25-39 which depend therefrom, independent claim 40 and claims 41-48 and 54-60 which depend therefrom, and independent claim 62 and claims 63, 64, 66, 67, 69-74 and 75-79 which depend therefrom, are not anticipated by Crosby.

**2. Claims 1-79 are non-obvious and patentable over Crosby under 35 U.S.C. § 103(a).**

The Examiner has rejected claims 1-79 under 35 U.S.C. § 103(a) as being unpatentable over Crosby. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.<sup>10</sup> The arguments presented above apply here as well. As discussed above, the independent claims from which all other claims on appeal depend, all include claim limitations directed to a prompt for a cardiac marker test not found in the cited art. As discussed in detail above, Crosby does not teach or

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<sup>9</sup> Crosby, para. 36, lines 11-15.

<sup>10</sup> In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

imply a method or system that includes a provision for providing a prompt to perform a cardiac marker test to a user.

The Examiner has argued that

As such, it would seem that a physical prompt would be an inherent part of the Crosby et al. system. Alternatively even if an actual prompt does not appear on a screen, or an audible or other prompt is given in this system, it would have been an obvious design choice to have altered the automatic steps of Crosby et al. to make them manual, or in a prompted order, given the fact that it is AHA protocol to perform the diagnostics in the order as claimed.<sup>11</sup>

The reasons why a prompt is not an inherent part of Crosby's teachings are discussed above. The Examiner's assertion that to alter the "automatic steps" of Crosby "to make them manual" would have been an obvious design choice is unfounded. First, the distinction made by the Examiner between "automatic steps" and "manual" steps is not at all clear. There is nothing in Crosby that teaches an automated device for performing Crosby's method. It appears that the Examiner's phrase "or in a prompted order" may be what the Examiner means by "manual", i.e., taking the steps of Crosby's method and putting them in a prompted order. Assuming this is what the Examiner means, there is no support for this assertion. The Examiner has alluded to an AHA guideline cited by Crosby as showing that "it is AHA protocol to perform the diagnostics in the order as claimed."<sup>12</sup> However, there is no requirement of a prompted ordering of steps in the claims on appeal. The Examiner also refers to the AHA document (not of record in this application) cited by Crosby saying:

The reference [Crosby] mentions past AHA documentation that indicates it is known protocol to first use ECG data for determining clinical symptoms as a first diagnostic, and then if the ECG is normal or not helpful, resorting to, i.e. prompting a physician to, performing cardiac marker tests as a second diagnostic tool.<sup>13</sup>

In this passage, the Examiner is misrepresenting the Crosby reference. Crosby does say that the AHA document provides guidelines to use ECG data as a first diagnostic, and then if the ECG is normal or not helpful, using necrosis markers as the next diagnostic tool.<sup>14</sup> But,

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<sup>11</sup> Final Action, page 3, lines 9-13.

<sup>12</sup> Final Action, page 3, line 14.

<sup>13</sup> Final Action, page 3, lines 1-5.

<sup>14</sup> Crosby, para. 58, lines 14-15.



Crosby does not say that the AHA guidelines indicate it is known to prompt a physician to perform these tests.

Crosby's method always includes an in vitro assay and the in vitro diagnostic test may be done at any point in the sequence of event, a prompt to give a cardiac marker test is not needed since a physician choosing to use Crosby's method will, by definition, know that an in vitro diagnostic test is needed to perform it (since it is an integral part of Crosby's diagnostic method), and the point in the process in which the physician performs this test doesn't matter. Providing a prompt would not be an obvious design choice to one skilled in the art looking at Crosby's system.

By providing a prompt, Applicant's method and apparatus makes possible the a system in which someone with less expertise than a physician and not carrying out the orders of a physician, can be given the direction needed to know if and when a cardiac marker test should be administered. Crosby's teachings, on the other hand, start at the point of assuming that some vitro test data is available, and proceeds from there to teach how the data can be used to diagnose. Crosby's teachings are not concerned with assisting someone in determining whether to administer a test. For at least these reasons, it cannot be said that the giving of a prompt to perform a cardiac marker test is an inherent part of the Crosby system, or a mere design choice in Crosby's teachings.

Thus, the cited reference fails to disclose or suggest the inventions defined by Applicants' claims on appeal, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention. For at least these reasons, the subject matters of claims 1-79 are not obvious in view of Crosby.

### CONCLUSION

For the reasons given above, rejections of claims 1-79 under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a) were erroneous and should be reversed. The Examiner has failed to meet the burden of establishing a prima facie case of anticipation and obviousness for all pending claims. In view of Appellants' arguments, the final rejections of claims 1-79 are improper and should be reversed.

Application Number 10/762,387  
Appeal Brief

Respectfully submitted,

Date: November 16, 2006

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## CLAIMS APPENDIX

1. An apparatus for documenting the myocardial ischemia of a patient's heart, the apparatus comprising:
  - an ECG monitor and data collector configured to receive electrocardial data about the patient's heart;
  - a cardiac marker data collector configured to receive cardiac marker data about the patient's heart; and
  - a data processing and recording module in electrical communication with said ECG monitor and data collector and said cardiac marker data collector and configured to record said electrocardial data and said cardiac marker data, and to generate a prompt to a user to perform a cardiac marker test.
2. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, said data processing and recording module comprising at least one of a processor and a memory device.
3. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, wherein the apparatus further comprises a user interface configured to permit entry of said cardiac marker data for receipt by said cardiac marker data collector.
4. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, wherein said data processing and recording module is configured to diagnose myocardial ischemia based on said electrocardial data.
5. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 4, wherein said data processing and recording module is configured to diagnose myocardial ischemia based on said electrocardial data and said cardiac marker data.

6. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 5, wherein said data processing and recording module is configured to suggest a treatment for myocardial ischemia based on said electrocardial data and said cardiac marker data.

7. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, the apparatus further comprising a display module in electrical communication with said data processing and recording module and configured to display at least one of said electrocardial data and said cardiac marker data.

8. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 7, wherein said data processing and recording module is configured to suggest a treatment for myocardial ischemia based on said electrocardial data and said cardiac marker data and said display module is configured to display said suggested treatment.

9. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 7, said display module comprising at least one of a visual display and a printer.

10. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, the apparatus further comprising an interpretive ECG algorithm module in electrical communication with said data processing and recording module.

11. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, wherein said data processing and recording module is configured to detect a change over time of said electrocardial data.

12. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, wherein said data processing and recording module is configured to detect a change over time of said electrocardial data and said cardiac marker data.

13. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, wherein said cardiac marker data collector is configured to identify a time and a date of receipt of said cardiac marker data.

14. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 10, wherein said data processing and recording module is configured to generate the prompt to the user of the apparatus to perform the cardiac marker test in response to a result of an ECG analysis performed by the interpretive ECG algorithm module.

15. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, wherein said prompt comprises at least one of a visual signal and an auditory signal.

16. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, wherein said data processing and recording module is configured to monitor a time period for performing a cardiac marker test on the patient and to generate a request for results of said cardiac marker test when said time period has expired.

17. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, the apparatus further comprising a patient data collector that is in electrical communication with said data processing and recording module and is configured to receive patient data comprising at least one of a name of the patient, an identification number of the patient, an age of the patient, a sex of the patient, and a race of the patient.

18. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 17, wherein the apparatus further comprises a user interface configured to permit entry of said patient data for receipt by said patient data collector.

19. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, the apparatus further comprising at least one patient parameter monitor and collector that is in electrical communication with said data processing and recording module and that is configured to receive data regarding a physiological state of the patient.

20. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 19, wherein said data regarding a physiological state of the patient comprises at least one of a heart rate of the patient, a blood pressure of the patient, a hemoglobin oxygen saturation of the patient, and an end-tidal carbon dioxide of the patient.

21. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, the apparatus further comprising a housing enclosing said ECG monitor and data collector, said cardiac marker data collector and said data processing and recording module.

22. A method for documenting the myocardial ischemia of a patient's heart, the method comprising:  
obtaining electrocardial data about the patient's heart;  
providing a prompt for the performance of a cardiac marker test;  
receiving results of said cardiac marker test performed on the patient;  
storing said electrocardial data and said results of said cardiac marker test in a patient report; and  
displaying said patient report.

23. The method for documenting the myocardial ischemia of a patient's heart of claim 22, the step of displaying said patient report comprising displaying said patient report on a visual display.

24. The method for documenting the myocardial ischemia of a patient's heart of claim 22, the step of displaying said patient report comprising printing said patient report.

25. The method for documenting the myocardial ischemia of a patient's heart of claim 22, the method further comprising the step of identifying a time and a date of receipt of said cardiac marker data and storing said time and said date in said patient report.

26. The method for documenting the myocardial ischemia of a patient's heart of claim 22, the method further comprising the step of obtaining data regarding the physiological state of the patient.

27. The method for documenting the myocardial ischemia of a patient's heart of claim 26, the step of obtaining data regarding the physiological state of the patient comprising obtaining at least one of a heart rate of the patient, a blood pressure of the patient, a hemoglobin oxygen saturation of the patient and an end-tidal carbon dioxide of the patient.

28. The method for documenting the myocardial ischemia of a patient's heart of claim 26, the method further comprising the step of storing said data regarding the physiological state of the patient in said patient report.

29. The method for documenting the myocardial ischemia of a patient's heart of claim 22, the method further comprising the step of providing said prompt for the performance of said cardiac marker test in response to a result of an analysis of said electrocardial data.

30. The method for documenting the myocardial ischemia of a patient's heart of claim 22, the method further comprising the step of analyzing said electrocardial data to determine if myocardial ischemia is suggested by said electrocardial data.

31. The method for documenting the myocardial ischemia of a patient's heart of claim 30, the method further comprising the step of providing a notification that myocardial ischemia is diagnosed in the patient if said electrocardial data suggests myocardial ischemia.

32. The method for documenting the myocardial ischemia of a patient's heart of claim 30, the method further comprising the step of analyzing said electrocardial data to determine the severity of myocardial ischemia of the patient's heart.

33. The method for documenting the myocardial ischemia of a patient's heart of claim 30, the method further comprising the step of providing the prompt for the performance of a cardiac marker test if said electrocardial data suggests myocardial ischemia.

34. The method for documenting the myocardial ischemia of a patient's heart of claim 30, the method further comprising the step of analyzing said electrocardial data and said cardiac marker data to determine if myocardial ischemia is suggested by said electrocardial data and said cardiac marker data.

35. The method for documenting the myocardial ischemia of a patient's heart of claim 22, the method further comprising the step of analyzing said electrocardial data to detect a change over time of said electrocardial data.

36. The method for documenting the myocardial ischemia of a patient's heart of claim 22, the method further comprising the step of analyzing said electrocardial data and said cardiac marker data to detect a change over time of said electrocardial data and said cardiac marker data.

37. The method for documenting the myocardial ischemia of a patient's heart of claim 22, the method further comprising the steps of monitoring a time period for performing



a cardiac marker test on the patient and generating a request for results of said cardiac marker test when said time period has expired.

38. The method for documenting the myocardial ischemia of a patient's heart of claim 22, the method further comprising the step of receiving patient data comprising at least one of a name of the patient, an identification number of the patient, an age of the patient, a sex of the patient, and a race of the patient.

39. The method for documenting the myocardial ischemia of a patient's heart of claim 38, the method further comprising the step of storing said patient data in said patient report.

40. An apparatus for documenting the myocardial ischemia in a patient's heart, the apparatus comprising:

- means for receiving electrocardial data about the patient's heart;
- means for receiving cardiac marker data about the patient's heart;
- means for processing said electrocardial data and said cardiac marker data, wherein said means for processing said electrocardial data and said cardiac marker data comprises means for generating a prompt to a user of the apparatus to perform a cardiac marker test;
- means for recording said electrocardial data and said cardiac marker data into a patient record; and
- means for displaying said patient record.

41. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, said means for processing said electrocardial data and said cardiac marker data comprising a processor.

42. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, said means for recording said electrocardial data and said cardiac marker data comprising a memory device.

43. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, wherein the apparatus further comprises means for permitting entry of said cardiac marker data for receipt by said cardiac marker data collector.

44. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 43, wherein said means for permitting entry of said cardiac marker data comprises one of a keyboard, a keypad and a touch screen.

45. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, wherein said means for processing said electrocardial data and said cardiac marker data further comprises means for diagnosing myocardial ischemia based on said electrocardial data.

46. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, wherein said means for processing said electrocardial data and said cardiac marker data further comprises means for diagnosing myocardial ischemia based on said electrocardial data and said cardiac marker data.

47. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 46, wherein said means for processing said electrocardial data and said cardiac marker data further comprises means for suggesting a treatment for myocardial ischemia.

48. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 47, wherein said means for displaying said patient record further comprises means for displaying said suggested treatment.

49. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, said means for displaying said patient record comprises at least one of a visual display and a printer.

50. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, the apparatus further comprising means for interpreting said electrocardial data, said means for interpreting said electrocardial data in electrical communication with said means for processing said electrocardial data and said cardiac marker data.

51. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, wherein said means for processing said electrocardial data and said cardiac marker data comprises means for detecting a change over time of said electrocardial data.

52. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, wherein said means for processing said electrocardial data and said cardiac marker data comprises means for detecting a change over time of said electrocardial data and said cardiac marker data.

53. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, wherein said means for receiving cardiac marker data comprises means for identifying a time and a date of receipt of said cardiac marker data.

54. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, wherein said means for processing said electrocardial data and said cardiac marker data comprises means for generating a prompt to a user of the apparatus to perform a cardiac marker test in response to an analysis of said electrocardial data.

55. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, wherein said prompt comprises at least one of a visual signal and an auditory signal.

56. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, wherein means for processing said electrocardial data and said cardiac marker data comprise means for monitoring a time period for performing a cardiac marker test on the patient and means for generating a request for results of said cardiac marker test when said time period has expired.

57. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, the apparatus further comprising means for collecting patient data, wherein said means for collecting patient data is in electrical communication with said means for processing said electrocardial data and said cardiac marker data, and wherein said means for collecting patient data comprises means for receiving patient data comprising at least one of a name of the patient, an identification number of the patient, an age of the patient, a sex of the patient, and a race of the patient.

58. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 57, wherein the apparatus further comprises means for permitting entry of said patient data for receipt by said means for collecting patient data.

59. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, the apparatus further comprising at least one means for collecting patient parameter data, wherein said at least one means for collecting patient parameter data is in electrical communication with said means for processing said electrocardial data and said cardiac marker data, and wherein said at least one means for collecting patient parameter data comprises means for receiving data regarding a physiological state of the patient.

60. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 59, wherein said data regarding a physiological state of the patient comprises at least one of a heart rate of the patient, a blood pressure of the patient, a hemoglobin oxygen saturation of the patient and an end-tidal carbon dioxide of the patient.

61. The apparatus for documenting the myocardial ischemia of a patient's heart of claim 40, the apparatus further comprising a housing enclosing at least a portion of said means for receiving electrocardial data about the patient's heart, said means for receiving cardiac marker data about the patient's heart and said means for processing said electrocardial data and said cardiac marker data.

62. A medical apparatus of the type that is configured to monitor the electrocardiogram waveform of a patient, the medical apparatus comprising:  
a cardiac marker data collector configured to receive cardiac marker data about the patient's heart;  
a data processor in electrical communication with said cardiac marker data collector;  
a memory module in electrical communication with said data processor and configured to record said electrocardiogram waveform and said cardiac marker data; and  
a display module in electrical communication with said data processor and configured to display at least one of the electrocardiogram waveform and said cardiac marker data,  
wherein said data processor is configured to generate a prompt to a user of the apparatus to perform a cardiac marker test.

63. The medical apparatus of claim 62, wherein the apparatus further comprises a user interface configured to permit entry of said cardiac marker data for receipt by said cardiac marker data collector.

64. The medical apparatus of claim 62, wherein said data processor is configured to diagnose myocardial ischemia based on the electrocardiogram waveform and said cardiac marker data.

65. The medical apparatus of claim 62, wherein said data processor is configured to diagnose myocardial ischemia based on the electrocardiogram waveform.

66. The medical apparatus of claim 64, wherein said data processor is configured to suggest a treatment for myocardial ischemia based on the electrocardiogram waveform and said cardiac marker data.

67. The medical apparatus of claim 66, wherein said display module is configured to display said suggested treatment.

68. The medical apparatus of claim 62, said display module comprising at least one of a visual display and a printer.

69. The medical apparatus of claim 62, wherein said data processor is configured to detect a change over time of said electrocardiogram waveform.

70. The medical apparatus of claim 62, wherein said data processor is configured to detect a change over time of said cardiac marker data.

71. The medical apparatus of claim 62, wherein said cardiac marker data collector is configured to identify a time and a date of receipt of said cardiac marker data.

72. The medical apparatus of claim 62, wherein said data processor is configured to generate a prompt to a user of the apparatus to perform a cardiac marker test, based on said electrocardiogram waveform.

73. The medical apparatus of claim 62, wherein said prompt comprises at least one of a visual signal and an auditory signal.

74. The medical apparatus of claim 62, wherein said data processor is configured to monitor a time period for performing a cardiac marker test on the patient and to generate a request for results of said cardiac marker test when said time period has expired.

75. The medical apparatus of claim 62, the medical apparatus further comprising a patient data collector that is in electrical communication with said data processor and is configured to receive patient data comprising at least one of a name of the patient, an identification number of the patient, an age of the patient, a sex of the patient, and a race of the patient.

76. The medical apparatus of claim 75, wherein the medical apparatus further comprises a user interface configured to permit entry of said patient data for receipt by said patient data collector.

77. The medical apparatus of claim 62, the apparatus further comprising at least one patient parameter monitor and collector that is in electrical communication with said data processor and that is configured to receive data regarding a physiological state of the patient.

78. The medical apparatus of claim 77, wherein said data regarding a physiological state of the patient comprises at least one of a heart rate of the patient, a blood pressure of the patient, a hemoglobin oxygen saturation of the patient and an end-tidal carbon dioxide of the patient.

79. The medical apparatus of claim 62, the apparatus further comprising a housing enclosing at least a portion of said cardiac marker data collector, at least a portion of said data processor and at least a portion of said memory module.



## **EVIDENCE APPENDIX**

None.

## **RELATED PROCEEDINGS APPENDIX**

None.